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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,591	04/02/2004	Matti Sallberg	TRIPEP.23AUS2C1	4899

20995 7590 10/12/2006

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/817,591	SALLBERG ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-87* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed on 07/13/06. Claims 66-81 have been amended. New claims 82-87 have been added. Claims 1-35 were canceled. Claims 36-87, are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Restriction Requirement

During the interview with Attorney Eric Furman on May 16, 2005, the restriction was discussed. After discussed with the supervisory examiner, Bruce Campell, the claims including the linking claims are still examined to the elected virus of HCV, because the claims including the linking claims under the examination still render an outstanding rejection.

Terminal Disclosure (TD)

Applicants timely filed the TD over other Application No. 10,719,619 has been know ledged and approved. It effectively overcomes the previous double patenting rejection.

Declaration under 37 C.F.R. 1,132

1. The Declaration under 37 CFR 1.132 filed 1.132 has been acknowledged and it is insufficient to overcome the 112 1st paragraph rejection set forth in the last Office action.

Claim Rejections - 35 USC § 112

2. Claims 36-87 are still rejected under 35 U.S.C. 112, first paragraph, on the same ground as stated in the previous office action. Because while being enable for inducing an enhanced antibodies response against HCV NS3 by using the full length polynucleotide of SEQ ID NO: 16 carried by the plasmid NS3/NS4-pVAX in mice with an optimal concentration of rabivirin or the polynucleotide encoding the polypeptide of SEQ ID NO:

17, does not reasonably provide enablement for using few base pairs of nucleic acids of said polynucleotide, such as 24 mers or 30 mers of SEQ ID NO: 16 in combination with any concentration of rabivirin to produce same biological effect in any subject for any period time of treatment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

3. In response to the previous office action, Applicants has filed a ***Declaration under 37 C.F.R. 1,132.*** In the Declaration, Dr. Matti Sallberg submits that numerous HCV epitopes and the method for identifying HCV immunogenic epitope within the length of 8 –12 amino acids are known in the art. The field also understood that eight-contiguous amino acids of NS3 from HCV contains a T cell epitope, several epitopes as short as 8 amino acids were determined along HCV NS3/NS4A sequence. Accordingly, applicants insist that given Applicants' disclosure, a skilled artisan could readily practice the now claimed invention without experimentation.

3. The Declaration and Applicants' argument have been respectfully considered. However, it is not found persuasive. Although several HCV epitopes as well as the method for determining an HCV epitope is known in the art, the specification does not provide any example demonstrating that a very short nucleotide encoding an epitope having only 8 or 10 amino acids derived from the SEQ ID NO: 16 or 17 is able to induce an enhanced humoral and T cell immune response against the specific HCV antigen when it is administrated as a naked nucleic acid molecule in combination with rabivirin in any concentration. The specification does not provide a sufficient evidence to support that every short nucleotides of SEQ ID NO: 16 is such an immunogenic epitope, when it is used with rabivirin at any concentration, it is able to elicit an enhanced humoral and cellular immune responses at any time of the treatment with a subject as claims drafted.

4. The unpredictability for using rabivirin as an adjuvant is also described in the previous office action evidenced by Hulgren et al. rabivirin is generally considered as an immunosuppressive agent or immunomodulator, especially it suppresses the Th2 type immune response. It is also well known in the art that any drug exhibits its therapeutic benefit within a certain window of an optimal concentration. For example, the Hulgren et

al. teach that the treatment of mice with rabivirin at 1 to 100 μM reduces the activations of Th1 and Th2 immune responses in general (See Fig. 2).

5. The current specification only provides one example of using one plasmid encoding the full length NS3/NS4 polypeptide in combination with 3 dosages of rabivirin (0.1, 1 and 10 mg) in a mouse model, wherein the enhanced immune response is only observed in week 3 in the dosage of 10 mg. Whereas the broad scope of the claims reads on any short nucleotide of HCV or even any virus with any concentrations of rabivirin regardless of duration of the treatment.

6. Therefore, absence of sufficient evidence to support the broadly claimed invention in specification, the broad scope of the claims is considered to be unpredictable. It would have to require a person skilled in the art doing enormous unpredictable and non-routine works or undue experimentation to make and use the full scope of the invention.

7. To this context, the rejection is maintained.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

9. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

`10. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 36-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11,411,493.

12. Although the conflicting claims are not identical, they are not patentably distinct each from other because claim 1 of Application SN. 11,141,493 contains all limitations cited claims 36-40 in the current application. Therefore, it anticipates claims 36-40 of the current application.

13. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. **Applicants are reminded that although the *Double Patenting rejection is a new ground rejection, however, the rejection could not be made since applicants filed the application 11,411,493 on April 26, 2006, which is time after the first office action of current application was mailed on Feb. 27, 2006.***

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

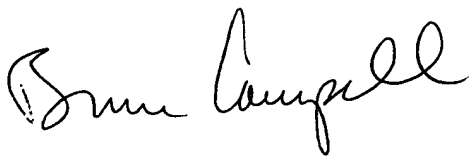
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 6:30 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Bao Qun Li
09/19/2006



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